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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,515	03/19/2004	Masayoshi Yamaguchi	671302-2006	7637
20999	7590	08/10/2005	EXAMINER	
FROMMER LAWRENCE & HAUG 745 FIFTH AVENUE- 10TH FL. NEW YORK, NY 10151			LIETO, LOUIS D	
			ART UNIT	PAPER NUMBER
			1632	
DATE MAILED: 08/10/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/804,515

Applicant(s)

YAMAGUCHI, MASAYOSHI

Examiner

Louis D. Lieto

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-40 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-19, drawn to a transgenic animal model to which a regucalcin gene is introduced and over expressed, a screening method of preventive and therapeutic agents, and a therapeutic agent, classified in class 800, subclass 8.
- II. Claims 1-12 and 20-24, drawn to a transgenic animal model to which a regucalcin gene is introduced and over expressed, a screening method of causative agents of disease, and a causative agent, classified in class 800, subclass 8.
- III. Claims 25-40, drawn to an animal model having bone pathology, wherein the animal model over expresses regucalcin and shows bone pathology, a screening method of preventive and therapeutic agents, and a therapeutic agent, classified in class 435, subclass 325.

The inventions are distinct, each from the other because of the following reasons:

inventions are distinct, each from the other because of the following reasons:

Inventions I, and II are patentably distinct inventions for the following reasons. In the instant case the different invention of group I is drawn to a transgenic animal model to which a regucalcin gene is introduced and over expressed, a screening method of preventive and therapeutic agents, and a therapeutic agent, while the invention of group II is drawn to a transgenic animal model to which a regucalcin gene is introduced and over expressed, a

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screening method of causative agents of disease, and a causative agent. The method of using the transgenic animal in group II, to identify a causative agents of disease, is quite different then the method of group I to identify preventive and therapeutic agents. Further the agents of each group of opposite effects. Finally, neither method can be used to identify the agent of the other.

Inventions II, and III are patentably distinct inventions for the following reasons. In the instant case the different inventions of groups I and II are drawn to a transgenic animal model to which a regucalcin gene is introduced and over expressed, while the invention of group III is drawn to an animal model having bone pathology, wherein the animal model over expresses regucalcin and shows bone pathology. The animal model of group III is not required to be a transgenic animal and could be derived through selective breeding practices. Further, by definition the transgenic animal of groups I and II comprises a transgene that is not required for the practice of the invention of group III. Finally, the invention of groups I and II must be made by a complex and difficult process, such as pro-nuclear injection, which is not required by the animal of group III.

Furthermore, searching the inventions of groups I, II and III together would impose a serious search burden. In the instant case, the search of a method of searching methods of identifying therapeutic or causative agents, said agents, a transgenic animal that over expresses regucalcin, and an animal that endogenously or inductively over expresses regucalcin are not co-extensive in the art. As such, it would be burdensome to search the inventions of groups I and II together.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Lou Lieto whose telephone number is (571) 272-2932. The examiner can normally be reached on Monday-Friday, 9am-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Patent applicants with problems or questions regarding electronic images that can be viewed in the PAIR can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Dr. Louis D. Lieto
Patent Examiner
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